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Navigating Therapy: Exploring FDA-Approved Treatments for Effective AAD Care

Announcer:

Welcome to CME on ReachMD. This episode is part of our MinuteCE curriculum.

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Dr. Portsteinsson:

This is CME on ReachMD and I'm Dr. Anton Porteinsson. Joining me today is Dr. Brendan Montano.

Let me review some of the data for FDA-approved therapies for agitation in Alzheimer's disease. Simply put, there's only one medication that is FDA approved for this indication, that is brexpiprazole. Brexpiprazole is a second-, some people say third-, generation atypical antipsychotic that is already approved for treatment of psychosis as well as mood disorders. And it was studied in 3 large clinical trials compared to placebo in patients with Alzheimer's disease and agitation and aggression. The studies basically showed that brexpiprazole, at either 2 milligrams daily or 3 milligrams daily, were effective in managing agitation and aggressive behaviors in Alzheimer's disease, and superior to placebo.

We saw this as measured by numerous outcomes, be that the Cohen-Mansfield agitation inventory, or the CMAI, where the drug, brexpiprazole, showed statistically significant separation from placebo, as well as in markers of disease severity, what we call the Clinician's Global Impression of severity.

It also translated into measures of caregiver burden. So, there was a broad sense of evidence of benefit of the medication for this purpose. But as we know, when we are treating older individuals with dementia, that can make them quite vulnerable to side effects. What about the safety profile? And the safety profile was quite benign. We didn't see much in terms of extra pyramidal symptoms or akathisia. We didn't see a difference in falls, in measures of liver function or kidney function, nor did we see evidence of cognitive worsening. So, it looked pretty reasonable on the safety and tolerability end.

What is important to understand for this medication is that you need to, by the FDA approved label, you need to start for one week at half a milligram a day, then go up to 1 milligram a day for one week, and then increase the dose to 2 milligrams. And that's one of the therapeutic beneficial dose. And if you need higher doses, you can go up to 3 milligrams.

So, Brendon, what has been your experience with using brexpiprazole for this purpose?

Dr. Montano:

Yes, and that has been the experience, most important, is to know that you need to get to 2 or 3 milligrams with, I agree, what looks in clinical research trials like very favorable outcomes when it comes to adverse events. Similar in many respects to placebo.

So, not to say that it can't happen in an individual patient, but there's been a reluctance for most primary care providers to use the atypical group of antipsychotics because they have fear about using an antipsychotic. And some of the older drugs in class have had problems and have black box warnings. In fact, like we say, they all have the black box warning, except that it's waived somewhat for brexpiprazole, which I'm very pleased with that the FDA decided to go that way. But the idea of, well, it's a big gun, I'll just use a little bit

of it. I'll use a low dose. That doesn't work. You need to get to that 2 or 3-milligram dose to get the results. And that's where I've been in my practice. That's where I've gotten good results. And it's been extremely well tolerated for the most part. And I think that, that being said, we're fortunate to have a drug that is approved for use in this area.

Dr. Porteinsson:

Thanks, Brendan. That's all the time we have. Thank you for listening and tuning in.

Announcer:

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